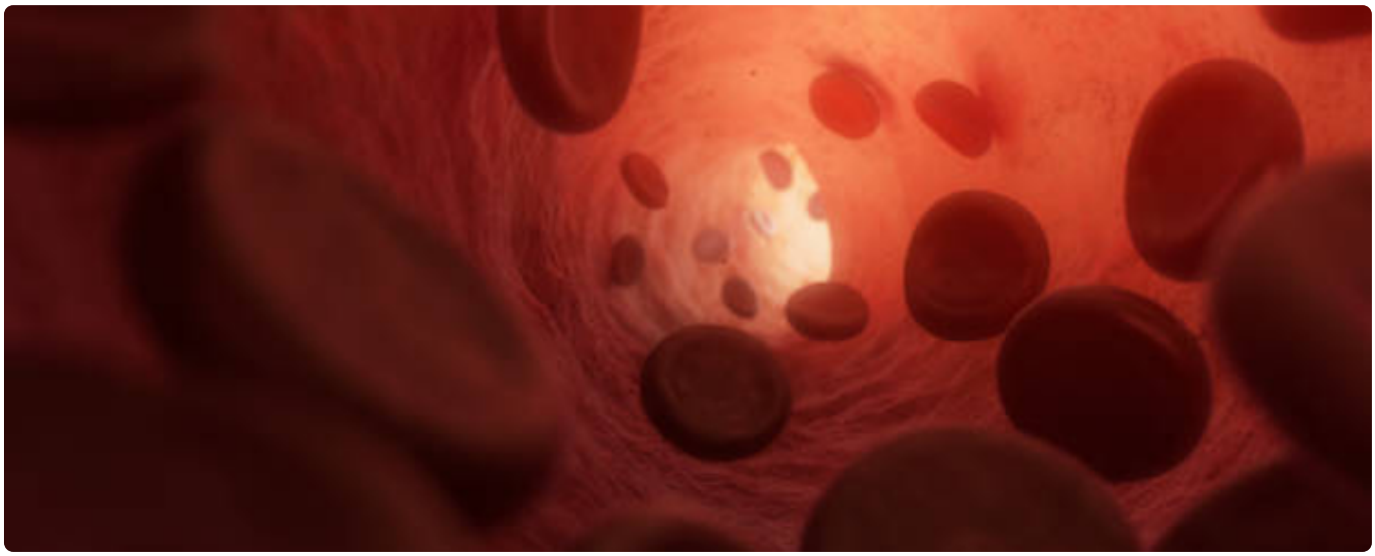

10/03/2021

Urgent Open Letter from Doctors and Scientists to the European Medicines Agency regarding COVID-19 Vaccine Safety Concerns

Letter

More

Doctors, scientists, lawyers and colleagues in allied disciplines can sign the open letter by sending their name, qualifications, areas of expertise and country of practice to: Doctors4CovidEthics@protonmail.com, with web verification (eg workplace or registration link, not for publication).

Emer Cooke, Executive Director, European Medicines Agency, Amsterdam, The Netherlands

28 February 2021

Dear Sirs/Mesdames,

FOR THE URGENT PERSONAL ATTENTION OF: EMER COOKE, EXECUTIVE DIRECTOR OF THE EUROPEAN MEDICINES AGENCY

As physicians and scientists, we are supportive in principle of the use of new medical interventions which are appropriately developed and deployed, having obtained informed consent from the patient. This stance encompasses vaccines in the same way as therapeutics.

We note that a wide range of side effects is being reported following vaccination of previously healthy younger individuals with the gene-based COVID-19 vaccines. Moreover, there have been numerous media reports from around the world of care homes being struck by COVID-19 within days of vaccination of residents. While we recognise that these occurrences might, every one of them, have been unfortunate coincidences, we are concerned that there has been and there continues to be inadequate scrutiny of the possible causes of illness or death under these circumstances, and especially so in the absence of post-mortems examinations.

In particular, we question whether cardinal issues regarding the safety of the vaccines were adequately addressed prior to their approval by the European Medicines Agency (EMA).

As a matter of great urgency, we herewith request that the EMA provide us with responses to the following issues:

1. Following intramuscular injection, it must be expected that the gene-based vaccines will reach the bloodstream and disseminate throughout the body [1]. We request evidence that this possibility was excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.

2. If such evidence is not available, it must be expected that the vaccines will remain entrapped in the circulation and be taken up by endothelial cells. There is reason to assume that this will happen particularly at sites of slow blood flow, i.e.

in small vessels and capillaries [2]. We request evidence that this probability was excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.

3. If such evidence is not available, it must be expected that during expression of the vaccines' nucleic acids, peptides derived from the spike protein will be presented via the MHC I — pathway at the luminal surface of the cells. Many healthy individuals have CD8-lymphocytes that recognize such peptides, which may be due to prior COVID infection, but also to cross-reactions with other types of Coronavirus [3; 4] [5]. We must assume that these lymphocytes will mount an attack on the respective cells. We request evidence that this probability was excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.

4. If such evidence is not available, it must be expected that endothelial damage with subsequent triggering of blood coagulation via platelet activation will ensue at countless sites throughout the body. We request evidence that this probability was excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.

5. If such evidence is not available, it must be expected that this will lead to a drop in platelet counts, appearance of D-dimers in the blood, and to myriad ischaemic lesions throughout the body including in the brain, spinal cord and heart. Bleeding disorders might occur in the wake of this novel type of DIC-syndrome including, amongst other possibilities, profuse bleedings and haemorrhagic stroke. We request evidence that all these possibilities were excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.

6. The SARS-CoV-2 spike protein binds to the ACE2 receptor on platelets, which results in their activation [6]. Thrombocytopenia has been reported in severe cases of SARS-CoV-2 infection [7]. Thrombocytopenia has also been reported in vaccinated individuals [8]. We request evidence that the potential danger of platelet activation that would also lead to disseminated intravascular coagulation (DIC) was excluded with all three vaccines prior to their approval for use in humans by the EMA.

7. The sweeping across the globe of SARS-CoV-2 created a pandemic of illness associated with many deaths. However, by the time of consideration for approval of the vaccines, the health systems of most countries were no longer under imminent threat of being overwhelmed because a growing proportion of the world had already been infected and the worst of the pandemic had already abated. Consequently, we demand conclusive evidence that an actual emergency existed at the time of the EMA granting Conditional Marketing Authorisation to the manufacturers of all three vaccines, to justify their approval for use in humans by the EMA, purportedly because of such an emergency.

Should all such evidence not be available, we demand that approval for use of the gene-based vaccines be withdrawn until all the above issues have been properly addressed by the exercise of due diligence by the EMA.

There are serious concerns, including but not confined to those outlined above, that the approval of the COVID-19 vaccines by the EMA was premature and reckless, and that the administration of the vaccines constituted and still does constitute "human experimentation", which was and still is in violation of the Nuremberg Code.

In view of the urgency of the situation, we request that you reply to this email within seven days and address all our concerns substantively. Should you choose not to comply with this reasonable request, we will make this letter public.

This email is copied to:

Charles Michel, President of the Council of Europe

Ursula von der Leyen, President of the European Commission.

Doctors and scientists can sign the open letter by emailing their name, qualifications, areas of expertise, country and any affiliations they would like to cite, to Doctors4CovidEthics@protonmail.com

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Yours faithfully,

Professsor Sucharit Bhakdi MD, Professor Emeritus of Medical Microbiology and Immunology, Former Chair, Institute of Medical Microbiology and Hygiene, Johannes Gutenberg University of Mainz (Medical Doctor and Scientist) (Germany and Thailand)

Dr Marco Chiesa MD FRCPsych, Consultant Psychiatrist and Visiting Professor, University College London (Medical Doctor) (United Kingdom and Italy)

Dr C Stephen Frost BSc MBChB Specialist in Diagnostic Radiology, Stockholm, Sweden (Medical Doctor) (United Kingdom and Sweden)

Dr Margareta Griesz-Brisson MD PhD, Consultant Neurologist and Neurophysiologist (studied Medicine in Freiburg, Germany, speciality training for Neurology at New York University, Fellowship in Neurophysiology at Mount Sinai Medical Centre, New York City; PhD in Pharmacology with special interest in chronic low level neurotoxicology and effects of environmental factors on brain health), Medical Director, The London Neurology and Pain Clinic (Medical Doctor and Scientist) (Germany and United Kingdom)

Professor Martin Haditsch MD PhD, Specialist (Austria) in Hygiene and Microbiology, Specialist (Germany) in Microbiology, Virology, Epidemiology/Infectious Diseases, Specialist (Austria) in Infectious Diseases and Tropical Medicine, Medical Director, TravelMedCenter, Leonding, Austria, Medical Director, Labor Hannover MVZ GmbH (Medical Doctor and Scientist) (Austria and Germany)

Professor Stefan Hockertz, Professor of Toxicology and Pharmacologym, European registered Toxicologist, Specialist in Immunology and Immunotoxicology, CEO tpi consult GmbH. (Scientist) (Germany)

Dr Lissa Johnson, BSc, BA(Media) MPsych(Clin) PhD, Clinical Psychologist and Behavioural Scientist, Expertise in the social psychology of atrocity, torture, collective violence and propaganda, former member, professional body Public Interest Advisory Group (Psychologist) (Australia)

Professor Ulrike Kämmerer PhD, Associate Professor of Experimental Reproductive Immunology and Tumor Biology at the Department of Obstetrics and Gynaecology, University Hospital of Würzburg, Germany, Trained molecular virologist (Diploma, PhD-Thesis) and Immunologist (Habilitation), Remains engaged in active laboratory research (Molecular Biology, Cell Biology (Scientist) (Germany)

Associate Professor Michael Palmer MD, Department of Chemistry (studied Medicine and Medical Microbiology in Germany, has taught Biochemistry since 2001 in present university in Canada; focus on Pharmacology, metabolism, biological membranes, computer programming; experimental research focus on bacterial toxins and antibiotics (Daptomycin); has written a textbook on Biochemical Pharmacology, University of Waterloo, Ontario, Canada (Medical Doctor and Scientist) (Canada and Germany)

Professor Karina Reiss PhD, Professor of Biochemistry, Christian Albrecht University of Kiel, Expertise in Cell Biology, Biochemistry (Scientist) (Germany)

Professor Andreas Sönnichsen MD, Professor of General Practice and Family Medicine, Department of General Practice and Family Medicine, Center of Public Health, Medical University of Vienna, Vienna (Medical Doctor) (Austria)

Dr Wolfgang Wodarg, Specialist in Pulmonary and Bronchial Internal Medicine, Hygiene and Environmental Medicine, Epidemiology, and Public Health; Honorary Member of the Parliamentary Assembly of the Council of Europe and former Head of the Health Committee of the Parliamentary Assembly of the Council of Europe; former Member of Parliament, German Bundestag; Initiator and Spokesman for

the study commission 'Ethics and Law in Modern Medicine'; Author and University Lecturer (Medical Doctor) (Germany)

Dr Michael Yeadon BSc (Joint Honours in Biochemistry and Toxicology) PhD (Pharmacology), Formerly Vice President & Chief Scientific Officer Allergy & Respiratory, Pfizer Global R&D; Co-founder & CEO, Ziarco Pharma Ltd.; Independent Consultant (Scientist) (United Kingdom)

Endorsing signatories

Dr Reem Abu-Sbaih, DO, Doctor of Osteopathy, Associate Professor Osteopathic Manipulative Medicine/ Neuromusculoskeletal Medicine (Medical Doctor) (USA)

Dr Véronique Ahari, General Practitioner (France)

Dr. Elizabeth Bastian, BSc (Genetics and Microbiology), MDCM, Family Medicine, General Practitioner in Oncology, sub specialty trained in Palliative Care (Medical Doctor) (Canada)

Dr Michael D Bell, MB, ChB (1978 Edinburgh) MRCGP (1989), General Practitioner (Medical Doctor) (United Kingdom)

Rev. Reuben P. Bell, DO, MS, MDiv, PhD, Osteopathic family physician since 1982, Bachelors and Masters degrees in Zoology, Professor of Biology (including Molecular Genetics and Developmental Biology) at the Bryn Athyn College of the New Church, 1989–1998, M.Div. and Ph.D. in theological studies, with attention to issues of science and religion (Medical Doctor and Scientist) (USA)

Dr Francisco Lacruz Bescos, MD, PhD, Consultant Neurologist with special training and dedication to Neuroimmunology and Multiple Sclerosis (Retired) (Medical Doctor) (Spain)

Dr Thomas Binder, MD, specialised in Cardiology and Internal Medicine, thesis in Immunology and Virology, with 32 years experience in diagnosis and treatment of Acute Respiratory Illness (Medical Doctor) (Switzerland)

Sarah Binns, MA VetMB, MS, MRCVS, MSc, PhD, DipLSHTM, Former Veterinary Infectious Disease Epidemiologist (United Kingdom)

Dr Rainer Bliefert, Dentist (Switzerland)

Dr Rachel Brown, MBChB, LLM (Medical Law & Ethics), MRCPsych CFMP, Consultant Psychiatrist (Medical Doctor) (United Kingdom)

Dr Roxana Bruno, PhD in Immunology, Researcher in Biochemistry, Immunology, Neuroinmunology and Genetics (Scientist) (Argentina)

Dr Elizabeth Burton, MBChB, General Medical Practitioner (Retired)(Medical Doctor) (United Kingdom)

Dr Ronald S. Carlson, AB Chem/Bio, DDS, Dentist (USA)

Dr Vernon Coleman, MB, ChB, General Practice Principal (Retired) (Medical Doctor) (United Kingdom)

Dr David Critchley, BSc, PhD, Clinical Research Scientist with more than 30 years experience, including projects in Virology and Immunology (Scientist) (United Kingdom)

Professor Barbara A Crothers, DO, Associate Professor, Pathology, Gynecologic, Breast and Cytopathology (USA)

Dr Rita Darby, General Practitioner (Medical Doctor) (Wales)

Dr. Daniel de la Torre Llorente, Biology Professor, Biotechnology-Plant Biology Department. Agronomic, Food and Biosystems Engineering School (ETSIAAB) Universidad Politécnica de Madrid (Scientist) (Spain)

Dr Nyjon Eccles, BSc, MBBS, MRCP, PhD, Specialist in Functional & Environmental Medicine (United Kingdom)

Dr Kjetil H. Elvevold, Senior Scientist, worked as Senior Scientist in a Contract Research Organization (CRO) in Norway that performed pre-clinical experiments for the pharmaceutical industry (Scientist) (Norway)

Dr Andreas Emmert, Specialist in Microbiology, Head Physician at Østfold Regional Hospital, Norway (Medical Doctor) (Norway)

Merit Enckell, Civ. Ing, PhD, Independent researcher, Structural Health Monitoring and Emerging Technologies, Formerly of KTH Royal Institute of Technology (Scientist) (Sweden)

Dr Radimé Farhumand, Specialist in Anesthesia (Medical Doctor) (Germany)

Dr Thomas Faulkner, MChiro, DC, Managing Director and Chiropractor (United Kingdom)

Dr Susan Flett, Specialist in Psychiatry, Child Psychiatry and Psychotherapy (Semi-retired) (Medical Doctor) (United Kingdom)

Dr Konstantinos Fountzoulas, MD, PGDiP Orth Eng., FEBOT, FRCS (Tr & Orth), Consultant Trauma and Orthopaedic Surgeon (Medical Doctor) (England and Italy)

Dr Carrie Ganek, MD, Adult Psychiatry (Medical Doctor) (USA)

Dr Martin E Ganek, MD, Board Certified Paediatrician (Medical Doctor) (USA)

Dr Parisi Giovanni, Specialist in Ophthalmology and Sports Medicine (Medical Doctor) (Italy)

Dr Céline Guérin, PhD in Neurosciences, Master in Microbiology and Genetics (Scientist-Practitioner) (France)

Dr. Olga Petrovna Guzova, Pediatrician, Dermatologist and Dermatopathologist (Medical Doctor) (Panama)

Dr Roman Häussler, General Medicine (Austria)

Dr Jutta Heinrich-Nols, Doctor and Clinical Pharmacologist (Medical Doctor and Scientist) (Germany)

Dr April M. Hurley, MD, Family Physician for 35 years (Medical Doctor) (USA)

William Ip, BSc. MIBMS, Former NHS Biomedical Scientist (Specialist in Microbiology), for over 30 years (Sicentist) (United Kingdom)

Dr Hervé Janecek, Veterinarian (France)

Jerzy Jaskowski, MD, PhD, MS, Specialties in General Surgery, Environmental Medicine, Physics and Biophysics (Retired)(Medical Doctor and Scientist) (Poland)

Dr. Elisabeth Jenik, General Medicine, Occupational Medicine and Psychosomatic Medicine (Medical Doctor) (Austria)

Dr Alain Joseph, General Medicine Specialist (Retired) (Medical Doctor) (France)

Dr Konstantinos Kakleas, MD, MRCPCH, MSc, PhD, Paediatric Allergy Consultant, Leicester Royal Infirmary Hospital (Medical Doctor) (United Kingdom)

Dr Hootan Kazemi, BDS Dental Surgeon, MSc(Distinc.) Clinical Biochemistry, BSc(Hons) Physiology (General Dental Practitioner) (United Kingdom)

Dr Ingrid Kiesel, Specialist in Psychiatry, Psychotherapy and General Medicine (Medical Doctor) (Germany)

Dr Wiltrud Kling, Specialist in General Medicine (Medical Doctor) (Germany)

Dr Ewa Konik, MD, Heart Transplant Cardiologist (Medical Doctor) (USA)

Dr Doris Krien, Assistant Doctor, Günzburg District Hospital (Medical Doctor) (Germany)

Brigitte Lacroix, clinical PKPD and PBPK modeler (Pharma industry), PhD in Pharmacy (Paris XI University), PhD in Pharmacometrics (Uppsala University)

(Scientist) (France, Sweden)

Dr Andreas Lang, MD (Medical Doctor) (Germany)

Dr Paul Laursen, PhD, Adjunct Professor, AUT University (Scientist) (New Zealand and Canada)

Dr Michael S Lavender, Consultant Anaesthetist (Medical Doctor) (Australia)

Dr Tess Lawrie, MBBCh, PhD, Guideline methodologist and evidence synthesis expert, Director of The Evidence Based Medicine Consultancy Ltd, Bath UK. Honorary Researcher at the Royal United Hospital, Bath UK (Medical Doctor and Scientist) (United Kingdom)

Dr Bronia Lee, MBBCh, MRCGP, Retired General Practitioner (Medical Doctor) (United Kingdom)

Dr Katrina Lewis, MD, BSc in Immunology and Physiological Chemistry, triple Board certified (USA) in Anesthesiology, Pain Medicine and Functional Medicine (Medical Doctor) (South Africa, USA)

Dr Derek Lohan, Consultant Radiologist and Director, Helix Radiology (Medical doctor) (Ireland)

Dr. Adele Lorigan, BSC (Chiro), Chiropractor (Australia)

Dr Antje Lueg, Specialist in Opthamology (Medical Doctor) (Germany)

Dr Kulvinder S. Manik, MBChB, MA, LLM, MRCGP, GP (Medical Doctor) (England)

Dr. Rosemarie Mayr, Specialist in Psychiatry and Psychotherapeutic Medicine and Child and Adolescent Psychiatry, ÖÄK Diploma for Homeopathy (Retired) (Medical Doctor) (Germany)

Dr Janet Menage, MA, MB, ChB, General Medical Practitioner (Retired) Qualified Psychological Counsellor (Medical Doctor) (United Kingdom)

Dr Niall McCrae, PhD, MSc, RMN, Mental health researcher, Psychiatric Nurse (United Kingdom)

Professor Nathalie McDonell, MD, PhD (human genetics), Professor of Molecular and Cell Biology (Medical Doctor and Scientist) (France)

Dr Sabine de Monvallier, General Practitoner (Medical Doctor) (France)

Dr Amir Mortasawi, Physician and author (Germany)

Dr Souha Nasreddine, MD, Ob/Gyn, Graduated from the Free University of Brussels Belgium, Holistic Gynecology (Lebanon)

Dr Terezia Novotna, General Practitioner, Emergency Doctor, and Anesthesiologist in Training (Medical Doctor) (Austria)

Akhmetzhanova Tamara Nikolaevna, Therapist and Cardiologist, the Republican Medical Genetic Center, Ufa (Medical Doctor) (Russia)

Ole C G Olesen, Double specialist in General Surgery, as well as Orthopedic Surgery and Trauma (Medical Doctor) (Denmark, Norway, Sweden and United Kingdom)

Dr Waltraud Parta-Kehry, Biologist and Doctor for Gynaecology and Reproductive Medicine (Medical Doctor) (Germany)

Dr Arun Kumar Patel, MBBS, MPH, MRCPH, FFPH, Medical Public Health Specialist (Retired), NHS (Medical Doctor) (United Kingdom)

Dr. Cristina Pinho, MD, Gastroenterologist (Medical Doctor) (Portugal)

Dr Hélène Potrich, General Practitioner (Medical Doctor) (France)

Dr Fabio Quirici, Swiss Medical Association (Medical Doctor) (Switzerland)

Professor Denis Rancourt, PhD, Researcher, Ontario Civil Liberties Association, Member scientist, PANDA (Pandemics Data & Analysis), Retired former Full

Professor of Physics, University of Ottawa, with expertise in environmental nanoparticles, molecular science, molecular dynamics, statistical analysis methods and mathematical and epidemiological modelling (Scientist) (Canada)

Claudia Riempp, Psychologist and psychotherapist, expert in health education (Germany)

Dr Nicola Reiser, Anaesthetist and Intensive Care Physician, Senior Physician at the University Clinic UMEÅ (Medical Doctor) (Sweden)

Rhys Rogers, BSc, Physiotherapy, 12 years experience as a frontline Physiotherapist (United Kingdom)

Dr Tred J Rissacher, DC, Chiropractor specialising in obesity and diabetes (USA)

Professor Simon Ruijsenaars, Professor in Mathematical Physics, School of Mathematics, University of Leeds (Scientist) (United Kingdom)

Dr Sam Saidi, MB, ChB, BSc, FRCOG, PhD, University of Sydney (Medical Doctor and Scientist) (Australia)

Dr Pamela Shervanick, DO, Medical doctor and Doctor of Osteopathic Medicine, with specialization in Psychiatry (Medical Doctor) (USA)

Dr Guido Spanoghe, Gastroenterologist (Medical Doctor) (Belgium)

Dr Paul Steven Spradbery, Forensic and Research Biologist, Foundation for Science and Technology, Lisbon, Intertek Life Sciences, London (Scientist) (United Kingdom)

Dr Duncan Syme, MBBS, FRACGP, Dip Prac Derm University of Cardiff, Graduate Monash University 1987, General Practitioner (Medical Doctor) (Australia)

Dr Carol Taccetta, MD, FCAP (Fellow of the College of American Pathologists), Pharmaceutical Physician for over 25 years, specializing in drug safety (Medical Doctor) (USA)

Dr Noel Thomas, MA, MB, ChB, DCH, DObsRCOG, DTM&H, MFHom. Semi retired NHS GP and homeopath (Medical Doctor) (United Kingdom)

Dr Corinne Tilloy, General Practitioner, (Medical Doctor) (France)

Dr Gilbert Tominez, General Practitioner (Retired) (Medical Doctor) (France)

De Georgy Urushadze, Naturopathic Doctor, Pediatrician (Pirogov Russian National Medical University), Emergency Doctor, Physiotherapist, Homeopath, Researcher (Russia)

Dr Jasmina Vucic-Peev, PhD, studied in Freiburg, Germany, training in Psychiatry in Switzerland (Medical Doctor) (Germany, Switzerland, Portugal)

Dr Jo Waller, UK State registered Biomedical Scientist since 1990 (Scientist) (United Kingdom)

Dr Maja Waibel, Dermatologist with specialty in Melanoma prevention (Medical Doctor) (Germany)

Dr Gerard A Waters, Mb, Bch, BAO, MICGP, General Practitioner, Recently suspended from Irish medical register for refusing to administer C 19 vaccine and objecting to Covid lockdowns (Medical Doctor) (Ireland)

Dr Ronald Weikl, Gynecologist and General Practitioner (Medical Doctor) (Germany)

Dr Helen Westwood MBChB (Hons), MRCGP, DCH, DRCOG, GP (Medical Doctor) (United Kingdom)

Dr Madhu Wickremaratchi, MBChB, MRCP, Acute and General Medicine (United Kingdom)

Dr Clive Wilder-Smith, FRCP, AGAF, MD, Consultant Gastroenterologst, Director of Research (Medical Doctor) (Switzerland)

Thomas Robin Wilks, MA, BSc(Hons) FHEA, CPhys, MInstP, University Science Lecturer, Maths, Mathematical Modelling and Physics, Open University (Scientist) (United Kingdom)

Dr Christopher Wood, MBBS, Retired General Practitioner (Medical Doctor) (United Kingdom)

Signatures of Colleagues in Allied Disciplines relating to Ethics and Human Rights

Dr Violeta Sotirova, MPhil, PhD, Lecturer in English (United Kingdom)

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